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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,674	11/21/2001	Gordon L. Woods	2404-105	1175

6449 7590 12/31/2002

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EXAMINER

JIANG, SHAOJIA A

ART UNIT PAPER NUMBER

1617

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/989,674

Applicant(s)

WOODS, GORDON L.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-19, 26-60, 62 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-25 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action is a response to Applicant's response filed on October 11, 2002 in Paper No. 8. Currently, claims 1-63 are pending in this application.

It is noted in the previous Office Action dated May 21, 2002, claims 1-19, 26-60, and 62-63 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-25 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waalkes for reasons of record stated in the Office Action dated May 21, 2002.

Applicant's remarks filed on October 11, 2002 in Paper No. 8 with respect to this rejection of claims 20-25 and 61 made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant asserts that none of the cited references teaches or suggests the instant treatment of balancing the concentration of cadmium in body fluids and tissue of a human comprising administering cadmium to a human. However, as discussed in the previous Office Action, cadmium is known to be useful in a pharmaceutical composition and in the prevention or substantially reducing NDEA-induced tumor formation in the mouse liver or lung therein according to Waalkes. Waalkes also discloses the administration of cadmium ( $\text{CdCl}_2$ , oral or i.v.) in an amount of  $16 \mu\text{mol/kg}$ . Therefore, one of ordinary skill in the art would have reasonably expected that the administration of cadmium in a known amount would have a beneficial therapeutic effect on correcting a cadmium deficiency in a human suffering cadmium deficiency, absent evidence to the contrary. Moreover, as Applicant admits that cadmium actually is essential trace metal in humans (see page 3, 2<sup>nd</sup> paragraph), one ordinary skill in the art would reasonably expect that administering a specific amount of cadmium to a human suffering cadmium deficiency would correct cadmium deficiency in said human.

At the interview, the examiner asserts that mice are a good animal model for studying the effects of cadmium administration to humans since Waalkes employed mice as studying model. A skilled artisan would clearly acknowledge that it is well-known in pharmaceutical science that mice are a good animal model for studying the therapeutic effects of a pharmaceutical in human. Further, as discussed above, cadmium actually is essential trace metal in humans. Hence, one ordinary skill in the art would recognize that administering cadmium in amount below the toxic level to a human would have the reasonable expectation of success.

It is merely noted for the record that the expressions "a method of balancing the concentration of cadmium in body fluids and tissue of a human", "balance", "said unbalanced levels" in claims 20-25 and 61 render claims 20-25 and 61 unclear since these expressions are not understood to a skilled artisan, i.e., administering cadmium to a human may merely increase or maintain the plasma or serum levels of cadmium in a human if levels of cadmium in the body are lower than the normal range of cadmium in said human body (correcting a cadmium deficiency in a human), but is clearly unable to remove or decrease cadmium in a human body if the levels of cadmium in the body are higher than the normal range of cadmium in said human body.

Moreover, Applicant's results in the specification at pages 45-47 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art and but are not deemed persuasive. The results showing that the cadmium levels rise to normal in a human suffering cadmium deficiency after administering cadmium to said human, are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Therefore, the evidence presented in Examples herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

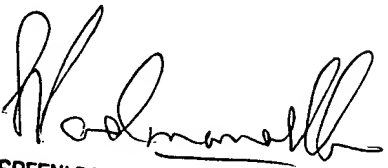
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
December 26, 2002

  
SREENI PADMANABHAN  
PRIMARY EXAMINER

~~SREENI PADMANABHAN  
PRIMARY EXAMINER~~

12/30/02